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10/808,210

03/24/2004

Richard T. Timmer

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11/15/2006

EXAMINER

BALASUBRAMANIAN, VENKATARAMAN

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ART UNIT

PAPER NUMBER

1624

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/808,210

Applicant(s)

TIMMER ET AL.

Examiner

Venkataraman Balasubramanian

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 August 2006.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-85 is/are pending in the application.
4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-3, 5, 14-19, 21, 30-32, 34, 43-45, 47, 56-58, 60, 69-71, 73 and 82-85 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 4/12/2006
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

Continuation of Disposition of Claims: Claims withdrawn from consideration are 4,6-13,20,22,33,35-42,46,48-55,59,61-68,72 and 74-81.

DETAILED ACTION

Applicant's response, which included amendment to claims 1, 2, 14, 30, 43 and 56 and addition of claims 84-85, filed on 8/24/2006, is made of record.

Claims 1-3, 5, 14-19, 21, 30-32, 34, 43-45, 47, 56-58, 60, 69-71, 73 and 82-85 are now under consideration.

Claims 4, 6-13, 20, 22-29, 33, 35-42, 46, 48-55, 59, 61-68, 72, 74-81 and 84 were withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected subject matter in the previous office action.

In view of applicants' filing of Terminal Disclaimer, all obviousness-type double patenting rejections made in the previous office action have been obviated. However, the following apply.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 5, 14-19, 21, 30-32, 34, 43-45, 47, 56-58, 60, 69-71, 73, 82-84 and 85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moriarty et al., WO 01/47897 for reasons of record. To repeat:

Moriarty et al., discloses several trisubstituted triazines as inhibitors of TNF- α . See formula shown on page 3 and note the definition of various variable groups. Also see pages 64-74 for general synthesis. Particularly note the definition of Y-R⁶, Z and R¹¹ overlap with instant Zx, R^{7a} and R^{2a}. Thus the compounds taught by Moriarty generically include instant compounds. See Table 1-4 shown on pages 75-102 for examples of triazine compounds made.

Instant claims require variously substituted triazine ring wherein the phenyl ring is substituted with specific groups wherein substituents included in the aryl ring is not CONH₂ as taught in Moriarty et al.

However, Moriarty et al., teaches the equivalency of exemplified compounds in Table 1-4 and general syntheses on pages 64-102 with those claimed with various

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substituents in the definitions of various variable groups on page 3. Thus it would have been obvious to one having ordinary skill in the art at the time of the invention was made to make compounds variously substituted in phenyl ring and the and the second amino group as permitted by the reference and expect resulting compounds to possess the uses taught by the art in view of the equivalency teaching outline above.

This rejection is same as made in the previous office action but now includes newly added claims. Applicants' argument to overcome this rejection is not persuasive.

Contrary to applicants' urging the genus of instant claims still include compounds of the genus of Moriarty et al. More specifically Zx group of instant claims include V-R⁶ choices, R^{2a} group of instant claims include Z choices of Moriarty et al., and R^{7a} group of instant claims include R¹¹ choices of Moriarty et al.

Thus genus of the instant claims read on the genus taught by Moriarty et al. Applicants had argued that the compounds exemplified by Moriarty et al., does not include the genus of instant compounds. This is not a persuasive argument. Moriarty et al., have adequately exemplified compounds, which will provide guidance to make the genus taught therein and there is requirement that all compounds of the genus should have been exemplified as urged by the applicants. In fact, Moriarty exemplified over 383 compounds which provide adequate guidance for one trained in the art to make these compounds based on the nucleophilic displacement of cyanuric halide with various nucleophiles taught therein.

Furthermore, it should be noted that applicants have not exemplified all compounds of the instant genus but a set of 100 compounds. Based on applicants' own

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analysis, it would appear that instant genus is also not enabled and that scope of the instant claims to be limited to 100 compounds.

As for applicants' argument that the Moriarty et al., teaches a "wish list" and "laundry list" is not a persuasive argument as Moriarty clearly teaches representative examples of the substituents in the triazine rings. The fact the breadth of the genus is large is not a criteria. It is the objective enablement and teaching of Moriarty et al. clearly provides objective enablement for compounds not exemplified base on that positively exemplified.

Again, if Moriarty et al., is not fully enabled then instant genus is also not fully enabled and would beg 112 first paragraph scope of enablement rejection based on applicants' reasoning that exemplified compounds do not lend enablement for the genus.

As for In re Geiger cited by the applicants, it is noted that the case relates to combinations of scale and corrosion preventing agents and hence it is not to the point. The issue at hand is objective enablement. It is held that based on the teachings of 383 exemplified compounds of Moriarty et al., one trained in the art would be able to make and use all compounds of the genus.

Hence, this rejection is proper and is maintained.

Claims 1-3, 5, 14-19, 21, 30-32, 34, 43-45, 47, 56-58, 60, 69-71, 73, 82, and 83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kamikubo et al. US 6,123,763.

In view of applicants' amendment, this rejection is deemed as obviated.

Claims 1-3, 5, 14-19, 21, 30-32, 34, 43-45, 47, 56-58, 60, 69-71, 73, 82, and 83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daeyaert et al. US 6,150,360.

In view of applicants' amendment, this rejection is deemed as obviated.

Claims 1-3, 5, 14-19, 21, 30-32, 34, 43-45, 47, 56-58, 60, 69-71, 73 and 82-85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Erickson et al. WO 01/47921 for reasons of record. To repeat:

Erickson et al. teaches several trisubstituted triazines, which include compounds of claimed in the instant claims, for the treatment of diabetes, asthma etc. See page 4, formula I, and note the definition of X, X¹, X², Y, R¹, R², R³ and R⁴. Note with these definitions, compounds taught by Erickson et al. corresponds to instant triazine with Zx, R^{7a} and R^{2a} groups. See pages 4 through 11 for preferred embodiments and pages 23-35 for process of making. See pages 36-54, Table 1 for compounds made.

Erickson et al. differs from the instant claims in not exemplifying all compounds generically taught and claimed.

However Erickson et al. teaches the equivalency exemplified examples of trisubstituted triazine core seen in Table 1 with those claimed therein in the definition of various variable groups of formula I. See definition of X, X¹, X², Y, R¹, R², R³ and R⁴. and preferred embodiments of these groups in pages 4-11.

Thus it would have been obvious to one having ordinary skill in the art at the time of the invention was made to make compounds variously substituted the triazine ring as

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permitted by the reference and expect resulting compounds (instant compounds) to possess the uses taught by the art in view of the equivalency teaching outline above.

This rejection is same as made in the previous office action but now includes newly added claims. Applicants' argument to overcome this rejection is not persuasive.

Contrary to applicants' urging the genus of instant claims still include compounds of the genus of Erickson et al. More specifically, Zx group of instant claims include R^3 - R^4 (wherein R^3 is H and R^4 is OR^{18} R^{18} being a hydrocarbon or heteroaryl) choices, R^{2a} group of instant claims include R^1 -N-Y choices of Erickson et al., and R^{7a} group of instant claims include R^2 (wherein $R^2 = R^7$ - R^6 -N- R^5) choices of Erickson et al.

Thus genus of the instant claims read on the genus taught by Erickson et al. Applicants had argued that the compounds exemplified by Erickson et al., does not include the genus of instant compounds. This is not a persuasive argument. Erickson et al., have adequately exemplified compounds, which will provide guidance to make the genus taught therein and there is requirement that all compounds of the genus should have been exemplified as urged by the applicants. In fact, Erickson exemplified over 164 compounds which provide adequate guidance for one trained in the art to make these compounds based on the nucleophilic displacement of cyanuric halide with various nucleophiles taught therein.

Furthermore, it should be noted that applicants have not exemplified all compounds of the instant genus but a set of 100 compounds. Based on applicants' own analysis, it would appear that instant genus is also not enabled and that scope of the instant claims to be limited to 100 compounds.

As for applicants' argument that the Erickson et al., teaches a "wish list" and "laundry list" is not a persuasive argument as Erickson et al., clearly teaches representative examples of the substituents in the triazine rings. The fact the breadth of the genus is large is not a criteria. It is the objective enablement and teaching of Erickson et al. clearly provides objective enablement for compounds not exemplified base on that positively exemplified.

Again, if Erickson et al., is not fully enabled then instant genus is also not fully enabled and would beg 112 first paragraph scope of enablement rejection based on applicants' reasoning that exemplified compounds do no lend enablement for the genus.

As for In re Geiger cited by the applicants, it is noted that the case relates to combinations of scale and corrosion preventing agents and hence it is not to the point. The issue at hand is objective enablement. It is held that based on the teachings of 164 exemplified compounds of Erickson et al., one trained in the art would be able to make and use all compounds of the genus.

Hence, this rejection is proper and is maintained.

Claims 1-3, 5, 14-19, 21, 30-32, 34, 43-45, 47, 56-58, 60, 69-71, 73, 82, and 83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Armistead et al. WO 01/25220.

In view of applicants' amendment, this rejection is deemed as obviated.

Election/Restrictions

This application contains claims 4, 6-13, 20, 22, 33, 35-42, 46, 48-55, 59, 61-68, 72 and 74-81 drawn to an invention nonelected with traverse in Paper dated 8/24/2006.

A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication from the examiner should be addressed to Venkataraman Balasubramanian (Bala) whose telephone number is (571) 272-0662. The examiner can normally be reached on Monday through Thursday from 8.00 AM to 6.00 PM. The Supervisory Patent Examiner (SPE) of the art unit 1624 is James O. Wilson, whose telephone number is 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAG. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-2 17-9197 (toll-free).


Venkataraman Balasubramanian

11/13/2006